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Department of Health  
OFFICE OF THE SECRETARY

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## ADVISORY

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### MEDICAL DEVICES CONTAINING DEHP PLASTICISED PVC

This is to inform the public regarding medical devices made of polyvinylchloride (PVC) containing Di(2-ethylhexyl)phthalate (DEHP).

DEHP is a type of plasticizer commonly used to soften PVC. DEHP is the preferred phthalate for medical devices because it remains flexible at low temperatures and is resistant to the high temperatures used during medical device sterilization. DEHP could be released when the device is heated or when the DEHP plasticized PVC is in contact with fluid.

Examples of medical devices using DEHP plasticized PVC are the following:

- intravenous (IV) bags and tubing
- umbilical artery catheters
- blood bags and infusion tubing
- enteral nutrition feeding bags
- nasogastric tubes
- peritoneal dialysis bags and tubing
- tubing used in cardiopulmonary bypass procedures
- tubing used in extracorporeal membrane oxygenation (ECMO)
- tubing used during hemodialysis

In laboratory studies, DEHP has been shown to have an effect on the reproductive system of rats and mice. At high dose levels, DEHP affects the development of the male reproductive system and the production of normal sperms in young rats and mice. However, several studies using monkeys have shown that, at extremely high dose levels, DEHP has no effect on the reproductive organs of monkeys.

"The United States Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) examined the potential risk of exposure posed to patients by comparing the dose of DEHP that patients might receive during various procedures to a 'Tolerable Intake' value for the compound. The following procedures have been identified as posing the highest risk of exposure to DEHP:

- exchange transfusion in neonates
- ECMO in neonates
- total parenteral nutrition in neonates (with lipids in PVC bag)
- multiple procedures in sick neonates (high cumulative exposure)
- hemodialysis in peripubertal males
- hemodialysis in pregnant or lactating women
- enteral nutrition in neonates and adults
- heart transplantation or coronary artery bypass graft surgery (aggregate dose)
- massive infusion of blood into trauma patient
- transfusion in adults undergoing ECMO."


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Phthalate is found almost everywhere. Non-medical examples are: building materials, household furnishings, clothing, cosmetics, pharmaceuticals, nutritional supplements, food packaging, automobiles, lubricants, waxes, cleaning materials and insecticides. Thus, everyone is exposed to small levels of phthalate through direct contact and use, indirectly through leaching from other products, or from general environmental contamination.

The Bureau of Health Devices and Technology (BHDT) of the Department of Health has the following advice to the public.

1. A person should not avoid a necessary medical procedure simply because of the possibility of health risks associated with DEHP exposure.
2. PVC-free alternatives (such as ethylene vinyl acetate, silicon, polyethylene or polyurethane) for IV bags, tubing, platelet storage, catheters, etc are now available. Health care facilities are advised to use these PVC-free products when the high-risk procedures requiring these products are to be performed, especially on the most sensitive groups, such as male neonates, pregnant women who are carrying male fetuses and peripubertal males.

The BHDT is currently reviewing its existing regulation regarding these products to determine how to further protect the public. For any queries please call the BHDT at telephone numbers nos. 743-8301 locals 3404, 3405, 3402.

  
**FRANCISCO T. DUQUE III, MD, M.Sc.**  
Secretary of Health

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